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<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER 0501-UTL-0 U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/559595</b>
INTERNATIONAL APPLICATION NO. PCT/US2004/017456	INTERNATIONAL FILING DATE May 28, 2004	PRIORITY DATE CLAIMED May 30, 2003
TITLE OF INVENTION Novel Methods and Compositions for Enhanced Transmucosal Delivery of Peptides and Proteins		
APPLICANT(S) FOR DO/EO/US John Ong, Gregg Stetsko, Robert Jennings		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
<b>Items 11 to 20 below concern document(s) or information included:</b>		
11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A preliminary amendment. 14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input checked="" type="checkbox"/> A substitute specification. 16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter. 17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/559595</b>		INTERNATIONAL APPLICATION NO. <b>PCT/US2004/017456</b>		ATTORNEY'S DOCKET NUMBER <b>0501-UTL-0</b>	
20. Other items or information: Substitute Specification - Marked-Up Version Sequence Listing on Compact Disk (2 copies) Compact Disk Transmittal Letter Statement Under 37 C.F.R. 1.821(f) Return Post Card					
The following fees have been submitted				<b>CALCULATIONS      PTO USE ONLY</b>	
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$ 300	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))				\$ 200	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0					
All other situations..... \$200					
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))				\$ 100	
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100					
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400					
All other situations..... \$500					
<b>TOTAL OF 21, 22 and 23 =</b>					
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
62 - 100 =	0 /50 =		x \$250	\$ 0	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	27 - 20 =	7	x \$ 50	\$ 350	
Independent claims	3 - 3 =	0	x \$200	\$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$ 0	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 950	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
<b>SUBTOTAL =</b>				\$ 950	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
<b>TOTAL NATIONAL FEE =</b>				\$ 950	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
<b>TOTAL FEES ENCLOSED =</b>				\$ 950	
				Amount to be refunded:	\$
				Amount to be charged	\$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 010535 in the amount of \$ 950.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 010535. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

the address associated with Customer  
Number 44638

James E. Butler  
SIGNATURE  
James E. Butler, Ph.D.  
NAME  
40931  
REGISTRATION NUMBER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**National Phase Filing of:**

**Intl. Appl. No.:** PCT/US2004/017456

**Inventors:** ONG, et al.

**Filed:** May 28, 2004

**Title:** NOVEL METHODS AND COMPOSITIONS FOR  
ENHANCED TRANSMUCOSAL DELIVERY OF  
PEPTIDES AND PROTEINS

**Confirmation No.:** Unknown

**TC/A.U.:** Unknown

**Examiner:** Unknown

**TRANSMITTAL**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The following documents are enclosed herewith for your review and consideration:

- Transmittal Letter to the US Designated/Elected Office Concerning a Submission Under 35 U.S.C 371 (In Duplicate) (3 pages)
- Substitute Specification, Claims and Abstract – Clean Version (58 pages)
- Substitute Specification, Claims and Abstract – Marked-Up Version (54 pages)
- Drawing Sheets (2 pages)
- Sequence Listing Statement Under 37 C.F.R. 1.821(f) (1 page)
- Compact Disk Transmittal Letter Under 37 C.F.R. 1.52(e) (1 page)
- Compact Disks containing Sequence Listing (2 Disks)
- Compact Disk containing Computer Readable Format of Sequence Listing (1 Disk)

CERTIFICATE OF MAILING  
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage in an envelope addressed to the Commissioner for Patents, Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, DC 20231

30 November 2005  
Date of Deposit

James Butler  
Name of Person Mailing Paper  
James Butler  
Signature of Person Mailing Paper

10/559595

Appln. No. 08/870,762  
Atty. Docket: 030639.0044.CPA2  
Page 2

**IAP9 Rec'd PCT/PTO 30 NOV 2005**

- Preliminary Amendment (2 pages)
- Combined Declaration and Power of Attorney (3 pages)
- Application Data Sheet (3 pages)
- Return Receipt Postcard

Respectfully submitted,  
AMYLIN PHARMACEUTICALS, INC.

Dated: November 30, 2005

By: James E. Butler  
James E. Butler, Ph.D.  
Registration No. 40,931

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